510(k) Summary
Seal Biopsy Valve – Reusable

DEC 2 0 2013

1. Company Identification

EndoChoice, Inc.
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Alpharetta, GA 30009
Telephone (678) 708 4743
FAX (678) 567 8218
Establishment Registration: 300759133

2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager

3. Device Name

Trade name:	Seal Biopsy Valve – reusable
Common/Usual Name:	Biopsy Valve
Classification name:	Endoscopic irrigation/suction system

4. Device Classification

Product Code:	OCX
Regulation Number:	876.1500
Class:	II
Classification Panel:	Gastroenterology/Urology

5. Intended Use

Reusable Seal Biopsy valves are intended to provide access for endoscopic device passage and exchange, help minimize leakage of biomaterial from the biopsy port throughout the endoscopic procedure, maintain insufflation, and provide access for irrigation.

6. Device Description

The Seal Reusable biopsy valve is composed of a cylindrical base and a connected cap. The device is designed to mount easily and seal securely on the biopsy port of endoscopes. It allows passage of instruments or devices of up to 3.2 mm in diameter, providing a seal both during use and following removal of the device. The Seal reusable biopsy valve is compatible with Olympus series 160, 180, and 190, Fujinon series 530, 590, and 600, and Fuse gastrointestinal endoscopes.

To use the device, the operator positions the device onto the instrument channel, pushing down on the cap and pressing the valve on the port until it fits snugly. Instruments of up to 3.2 mm in diameter may then be passed through the slit in the diaphragm of the valve.

The deformation of the material provides a seal around the introduced device. After the procedure, the instrument is withdrawn prior to removal of the biopsy seal from the port. Users are instructed to remove the cap from the seal prior to pre-cleaning.

By maintaining a seal at the biopsy port, the device allows irrigation access while allowing insufflation to be maintained, and it minimizes leakage of biomaterial from the biopsy port during the endoscopic procedure.

The Seal reusable biopsy valve is provided non-sterile. It does not bear single-use labeling, and includes steps for cleaning and disinfection in the instructions for use (see section 13, proposed labeling).

7. Substantial Equivalence

7.1. Predicate devices

The Seal reusable biopsy valve is substantially equivalent to the Seal Single Use biopsy valve (K111821) manufactured by EndoChoice. The intended use, design, materials and labeling are all substantially equivalent.

7.2. Intended Use

The indications for use the device under review is the same as the predicate device Seal single-use biopsy valve (K111821) manufactured by EndoChoice. Each device is indicated for use to provide access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

7.3. Technical Characteristics

Each of the three devices is comprised of a cylindrical main body and attached cap, and is designed to fit snugly on the biopsy port of a gastro-intestinal endoscope. The principle of operation of each is the same – an instrument is passed through a slit in a diaphragm, with the deformation of the elastomer creating a seal.

Materials are equivalent. The predicate Seal single-use biopsy valve is composed of Thermoplastic elastomer, which has similar elastic properties to silicone.

7.4. Performance Characteristics

The steps for operator use of each of the devices are equivalent. The device is manually pressed onto the biopsy port of the endoscope, sealing the channel and allowing for the passage of instruments while maintaining the seal and preventing a loss of insufflation.

8. Non-clinical testing

The following non-clinical testing has been performed on the Seal Biopsy valve – reusable:

- Benchtop functional performance testing

- Laboratory validation testing of the cleaning instructions
- Laborator validation testing of the high-level disinfection instructions
- Biocompatibility testing in conformance with ISO 10993-1.

All test results passed, demonstrating that the device is safe and effective in comparison with predicate devices.

9. Conclusion

The Seal Biopsy Valve – reusable is substantially equivalent to the predicate devices listed above. It is the same or equivalent in terms of design, intended use, materials, and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

EndoChoice, Inc.
Daniel Hoefer
Regulatory Affairs Manager
11810 Wills Road
Alpharetta, GA 30009

Re: K132776
Trade/Device Name: Seal™ Biopsy Valve - reusable
Regulation Number: 21 CFR 876.1500
Regulation Name: Biopsy Valve
Regulatory Class: Class II
Product Code: OCX
Dated: November 26, 2013
Received: November 27, 2013

Dear Daniel Hoefer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elaine Blyskun
for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132776

Device Name: Seal Biopsy Valve – reusable

Indications for Use:

The device is intended to provide access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of In Vitro Diagnostic Devices (OIVD)~~

Elaine Blyskun
for Benjamin Fisher